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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,627	02/26/2004	Howard Kaufman	19240.461	7662
56949	7590	01/28/2008		
WilmerHale/Columbia University			EXAMINER	
399 PARK AVENUE			SINGH, ANOOP KUMAR	
NEW YORK, NY 10022			ART UNIT	PAPER NUMBER
			1632	
			MAIL DATE	DELIVERY MODE
			01/28/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/789,627

Applicant(s)

KAUFMAN ET AL.

Examiner

Anoop Singh

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 5-7, 11-15, 18-21, 23-27, 29, 33, 35-37, 42-44, 50-52, 54-56, 60 and 65 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1, 5-7, 11-15, 18-21, 23-27, 29, 33, 35-37, 42-44, 50-52, 54-56, 60, 65 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Applicant's response and amendment to the claims filed November 15, 2007 has been received and entered. Applicants have amended claims 1, 5-7, 11, 13, 15, 18-21, 23, 26-27, 29, 33, 35-37, 42-44, 50, 52, 56, 60, 65, while claims 2-4, 8-10, 16-17, 22, 28, 30-32, 34, 38-41, 45-47, 53, 57-59, 61-64 have been canceled.

Applicant's election of claims 1-29, 33-61 and 65 (group V) drawn to a composition for delivering a therapeutic agent to a target cell, comprising a microorganism that has on its cell surface an exogenous molecule that binds the target cell and a therapeutic agent wherein the therapeutic agent is a nucleic acid and a method for using said composition in treating neoplasia in the reply filed on April 9, 2007 was acknowledged. Applicants also elected the following species: colon cancer cell, and carcinoembryonic antigen (CEA). Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 30-32 and 62-64 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on 4/9/2007. It is noted that applicants elected claims 1-29, 33-61 and 65 (group V) drawn to a composition for delivering a therapeutic agent wherein the therapeutic agent is a nucleic acid, while claims reading on other therapeutic, diagnostic or other preventive or contrasting agents listed in groups I-IV were not elected for prosecution.

It is noted that, in response to office action dated 5/18/07, applicants have amended claims 27 and 56 to include nucleic acid comprising a plasmid encoding a polypeptide selected from the group consisting of an anti-proliferation factor, an immuno-enhancing factor, a pro-apoptotic factor, and a pro-drug converting enzyme

that was not previously presented. Accordingly, a new election of species is required in view of amendments to the claim27.

Claims 1 , 5-7, 11-15, 18-21, 23-27, 29, 33, 35-37, 42-44, 50-52, 54-56, 60, 65, are under consideration.

Election/Restrictions

This application contains claims 27 and 56, directed to the following patentably distinct species: a nucleic acid comprising a plasmid encoding a polypeptide selected from the group consisting of an anti-proliferation factor, an immuno-enhancing factor, a pro-apoptotic factor, and a pro-drug converting enzyme. The species are independent or distinct because each nucleic acid encoding a polypeptide has a unique physical and chemical structure that would have different and distinct mechanism of action. Since, each of these have unique physical and chemical structure and could be used in many different biological assays that may not be coextensive in patent and non patent literature.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 33 are generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are

likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable

Application/Control Number:
10/789,627
Art Unit: 1632

Page 5

over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anoop Singh whose telephone number is (571) 272-3306. The examiner can normally be reached on 9:00AM-5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272- 4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anoop Singh
AU 1632

/Thaian N. Ton/
Primary Examiner
Art Unit 1632